May 7, 2004

Docket Number 2004S-0170: Medicare Prescription
Drug, Improvement, and Modernization Act of 2003, Section 1013: Suggested
Priority Topics for Research.

Department of Health and Human Services (HHS)
Steering Committee on Section 1013:

Pfizer respectfully submits these comments in response to the Agency for Healthcare Research and Quality's (AHRQ) request for comments on its initial activities under Section 1013 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).

Pfizer is a research-based pharmaceutical company with enormous experience applying objective data to clinical problems. We maintain the largest privately funded biomedical research establishment in the world, and have a global enterprise dedicated to obtaining, understanding, and applying the very best evidence from basic and clinical sciences to human health. This experience in the discovery and development of pharmaceuticals, and our keen understanding of the clinical environment in which our products are used, provides a unique perspective on the value and role of AHRQ's activities under MMA Section 1013.

Pfizer supports the stated goal of Section 1013, which is to support research to "improve the quality, effectiveness, and efficiency of health care delivered" to patients in the Medicare, Medicaid, and State Children Health Insurance (SCHIP) programs. As such, we endorse the comments submitted to the docket by the Pharmaceutical Research and Manufacturers of America (PhRMA).

Pfizer recognizes that policy makers must make health care resource allocation decisions, and that purchasers and consumers of health services are increasingly concerned with the value and quality of the care being provided. That said, Pfizer believes clinical judgment and patient choice, within the boundaries of accepted medical practice, must always be the overriding force in decisions about individual care. To provide quality, individualized care, physicians must have the opportunity for multiple treatment options. Dosing, packaging and different metabolic pathways may make particular compounds in a therapeutic class suitable for one person but not for another with the same condition.[1] As Pfizer Chairman and CEO Dr. McKinnell told the World Health Care Congress on January 28, 2004, Pfizer believes our health care system "should allow doctors and patients to choose the best courses of care … rather than settling for the lowest common denominator of 'average care for the average person.'"

[1] Gorman, L. Medicaid Drug Formularies. Independence Institute, Issue Paper Number 2-2002. April 2002.

Section 1013 calls on AHRQ to conduct studies to improve the quality, effectiveness, and efficiency in the Medicare, Medicaid and SCHIP programs. Under the statute, the studies must focus on (1) the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs); and (2) strategies for improving the efficiency and effectiveness of such programs, including the ways in which such items and services are organized, managed, and delivered under such programs. Notably, as stated by AHRQ in its request for comments, "the statute does not limit the scope of the initial priority list". Therefore, Pfizer believes AHRQ should look to improving the clinical return on overall money spent by examining disease management, prevention programs, and various other long-term strategies for treating chronic conditions in the context of its overall research agenda.

Pfizer believes additional research must be done on the comparative clinical effectiveness of treatments for the most costly disease states. We also believe it is essential to analyze and understand the underutilization of appropriate treatments by the patient populations most susceptible to these diseases.[2] To that end, for each disease state studied by AHRQ, Pfizer believes it is essential to study the disparate treatment of the disease in minority populations.

Health care spending is highly concentrated. Between 1995 and 1999 the most costly 5 percent of Medicare beneficiaries accounted for 47 percent of total Medicare spending.[3] During the same time period, the most costly 20 percent of beneficiaries accounted for 84 percent of spending. By contrast, the least costly 40 percent of beneficiaries accounted for 1 percent of spending.[4] For this reason, Pfizer believes it is essential that AHRQ focus its studies on the most costly diseases as well as on populations that tend to not receive appropriate care and therefore live less healthy lives. Therefore, the following areas are recommended for study, in that almost 90 percent of beneficiaries in the top 5 percent of annual Medicare spending had at least one of the following:

1. Heart disease
2. Cancer
3. Chronic kidney disease
4. Diabetes
5. Maternal and child health
6. Respiratory diseases
7. Long term care

Pfizer believes it would be advisable for AHRQ to further research the benefits of disease management. Disease management is "a system of viewing health care disease by

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[2] Please note, per AHRQ's request, these comments focus on pharmaceutical utilization/underutilization. Pfizer does, however, believe that in addition to these areas, AHRQ should utilize MMA Section 1013 to study other areas critical to improving quality and efficiency, such as coordination of care, information technology and health care delivery processes.

[3] Pfizer believes AHRQ should devote more resources to the study of waste in the Medicare system. For example, a recently published article by Fisher, et. al, *The Implications of Regional Variations in Medicare Spending*, notes that the overutilization of certain services, caused by the skewed apportionment of physicians throughout the United States is causing a drain on the Medicare system.

[4] See "Congressional Report on National and Medicare Spending" at:
http://www.medpac.gov/publications/congressional_reports/ Jun03DataBookSec5.pdf

disease and examining the interrelated elements in the treatment process with outcomes research to improve quality and lower costs."[5] We believe disease management systems should be in place for each disease state and that pharmaceutical outcomes research or comparative effectiveness analysis should be conducted in the context of all cost drivers. In this manner, a policymaker makes rational economic and clinical choices between therapeutic alternatives.

Finally, Pfizer believes AHRQ must be vigilant in ensuring that its studies are not misapplied to support inappropriate cost containment strategies. Only after patients and physicians are aware of clinical options and available outcomes data is it proper for issues of cost and coverage to enter into the decision. Restricting access to important medicines not only harms patients, but also inflates overall health care costs as a greater number of patients inevitably require costly hospital care and other medical services as a result of untreated and worsening conditions. AHRQ's overall mission is to improve the quality, safety, efficiency and effectivness of health care for all Americans. It is therefore critical that AHRQ utilize the resources provided under MMA Section 1013 to examine pharmaceuticals as part of a broader, patient-centered research agenda and provide data and communication processes that allow patient and caregivers to make key treatment decisions.

Pfizer thanks AHRQ for this opportunity to provide comments, and looks forward to working with the AHRQ as it implements MMA Section 1013.

Respectfully submitted,

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[5] See Castagnoli (1995).